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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,438	08/20/2001	Yoshiharu Matahira	01503/HG	6058

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/26/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,438

Applicant(s)

MATAHIRA ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,9,11-16,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7,9,11-16,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17/19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of Information Disclosure statement, Extension on of Time, Amendment E, and Rule 132 Declaration received July 7, 2003 is acknowledged. Claims 1, 3, 5-7, 9, 11-16, and 20-21 are pending in this application.

Response to Amendment

The Declaration under 37 CFR 1.132 filed July 7, 2003 is sufficient to overcome the rejection of claims 1 and 6 based upon Hageman et al (6,420,342).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-7, 9, 11-16, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al (5,965,596) in view of St. Cyr et al (6,159,942).

Harris et al teach a composition for increasing anaerobic work in tissues and teaches of creatine and beta-alanylhistidine in muscle content, leads to increased

muscle duration during exercise (col. 3, lines 35-46). Harris teaches administering chicken broth, which contains anserine and carnosine, to subjects (example 2). Harris teaches the additional use of creatine and carbohydrates, such as sugar, in the composition (claims).

Harris et al does not teach the inclusion of ribose.

St. Cyr et al teaches increasing energy availability in mammals with decreased energy by administering ribose (col. 3, lines 10-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Harris et al and St. Cyr et al since both teach a method and composition of increasing energy levels. One would be motivated to use anserine and ribose in a composition to obtain an additive effect since both reference teach the use of individual components to increase energy level in muscles. In the absence of showing otherwise, it is prima facie obvious to combine two composition each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. Further, since Harris et al teach the use of a sugar, clearly the compatibility of ribose and the dipeptide are seen.

Response to Arguments

Applicant argues that Harris et al administering beta-alanine along with L-histidine and creatine. It is argued however, that Harris does not specifically mention the ingestion of anserine. Further, it is argued that the chicken broth not only contains anserine but carnosine, collagen, amino acids, etc. Applicant argues that Harris does

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not teach a sufficient amount to control muscular fatigue. Secondly, applicant argues that Harris does not mention ribose specifically and although simple carbohydrates are mentioned, there are various sugars.

Applicant argues that St. Cyr et al only teach the administration of ribose. It is argued that the declaration demonstrates the unexpectedness and synergistic effect of anserine and ribose combination.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points to column 10 wherein Harris discloses "in one session, 8 milliliters per kilogram body weight of broth containing approximately 40 milligrams per kilogram body weight of beta-alanine (**e.g. in the form of anserine and carnosine**) was ingested." Clearly, Harris teaches the ingestion of anserine. Further, it is pointed out that Harris entire invention is focused on increasing the working capacity of muscles and "the method includes ingesting and infusing composition into the body. The compositions are mixtures of compounds capable of increasing the availability and uptake of creatine and of precursors for the synthesis and accumulation of beta-alanylhistidine dipeptides, in human and animal muscles." See column 2. Therefore, it is clear that anserine is utilized in an effective amount to increase work capacity in muscles.

In regards to the argument that the chicken broth contains several other components, the examiner points out that the claim language does not exclude other ingredients in the composition. In regards to the "consisting essentially of" language, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103,

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absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). The examiner refers to the specification for the defined scope of the phrase "consisting essentially of." It is clear that the basic and novel characteristics of the invention are not changed by the addition of other amino acids, sugars, vitamins, etc. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. Further, the applicant is referred to column 6, wherein Harris provides examples of compositions containing only beta-alanine (in the form of anserine/carnosine) and glucose.

In regards to the argument pertaining to the simple carbohydrates, the examiner points out that the secondary reference is relied upon to specifically teach ribose. Harris's teaching of the inclusion of simple carbohydrates such as glucose provides the premise and motivation for one to substitute other sugars with the expectation of similar results.

In regards to St. Cyr et al, this reference is relied to teach the use of ribose for the same purpose of increasing work performance of muscles. It is prima facie obvious

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to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See *In re Kerkhoven*.

In regards to the declaration under 37 CFR 1.132 filed October 3, 2002, it is insufficient to overcome the obviousness rejection. The declaration shows a significant difference when compared to the control; however a statistical evaluation between ribose by itself and anserine by itself are not seen. Therefore, it is unclear if the values represented are an additive effect of anserine and ribose or a synergistic effect of both components (ribose and anserine). In regards to applicant's request for clarification of this, the examiner points out that the figure merely shows an additive effect, which is in fact quite expected since the art clearly shows both components are used for the same purpose. The standard deviation of +/- ribose overlaps the anserine range. Further, the graph does not provide precise numerical evaluation of the swimming times. The applicant is requested to provide numerical values to the graph to verify a synergistic effect since this is not readily ascertained from the graphs. Lastly, the declaration does not establish the criticality and unexpected results of anserine versus other similar imidazole dipeptides.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



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